REMARKS

Applicants request reconsideration and withdrawal of the outstanding rejection based on the foregoing amendments and following remarks. Claim 32 has been amended. No new matter has been added.

Response to Rejections under 35 U.S.C. § 112

Claims 32-33 and 37-41 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states that claim 32 is unclear because, in the phrase "comprising distillers grains which have been fermented with yeast," it is not clear whether the phrase indicates an extra yeast fermentation on the distillers grains, which are already fermented by definition. By the present Amendment, Applicants have amended claim 32 in view of the Examiner's comments. Applicants respectfully submit that claim 32 now even more fully satisfies the requirements of the second paragraph of 35 U.S.C. § 112. Accordingly, favorable reconsideration and withdrawal of this rejection are respectfully requested.

Further, the Examiner asserts that claim 32 is unclear for reciting the phrase "blood sugar value." The Examiner asserts that it is not clear if "value" refers to the concentration of blood sugar or something else. Applicants respectfully disagree and traverse the rejection. Applicants respectfully submit that claim 32 is entirely clear with regard to blood sugar value because it recites the units of blood sugar value (mg/dl) in terms of concentration. Moreover, the phrase "blood sugar values" is a term of art and

is entirely clear to persons of ordinary skill in the art. The references provided with Applicants' previous response used the phrases "fasting blood sugar values" and "fasting blood sugar concentrations" interchangeably. Moreover, the international standard for measuring blood glucose levels is in terms of concentration. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner also asserts that claim 32 is unclear for reciting the phrase "thickening said distillers grains." The Examiner asserts that it is not clear if the thickening is by concentration, e.g., removal of water, or by adding a thickening agent. Firstly, Applicants believe that the Examiner has mistakenly listed claim 32 instead of claim 37 because claim 32 does not recite the cited phrase, but claim 37 does. Applicants submit that the phrase "thickening said distillers grains" is not unclear as the Examiner asserts because the distillers grains can be thickened by any suitable means. A person of ordinary skill would have been aware of several methods for thickening the grains as evidenced by the Examiner having listed two different methods in the Office Action on page 3. Thus, Applicants submit that there is no reason to unnecessarily limit the claims to a particular method of thickening, when any method known to a skilled person could be used. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim 32 was also rejected under 35 U.S.C. § 112 as being unclear for the recitation "in an amount effective to lower said patient's increased blood sugar value." The Examiner asserts that it is not clear whether the effect of administering the

composition is instantaneous or if it will be gradual when the composition is taken for a period of time. Applicants respectfully disagree and traverse the rejection. Applicants submit that it is inappropriate to require applicants to define pharmacokinetics in patent claims. It is well-known that each individual patient will react differently to treatment. Omission of the effective time scale does not render patent claims indefinite. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Response to Rejections under 35 U.S.C. § 102

Claims 32-33 and 37-41 remained rejected under 35 U.S.C. § 102(b) as being anticipated by Tölle (WO/2001/010245- English equivalent: U.S. 6,706,294). In response to Applicants' amendments and arguments, the Examiner maintains that Tölle disclosed every element of the presently claimed method. The Examiner states that Tölle disclosed the usefulness of the distillers grains for diabetic people and overweight people and that Tölle disclosed that the product should be consumed on a regular basis at least for a certain period of time. With regard to the method steps of determining the patient's blood sugar values, the Examiner asserts that Tölle discloses that the grains are beneficial for diabetics, i.e., patients who have already been diagnosed with the disease. Accordingly, the Examiner has not given added patentable weight to these method steps. Thus, the Examiner contends that the effect of lowered blood sugar and lowered triglyceride levels will be inherent to the consumption disclosed by Tölle. With regard to Applicants' argument that Tölle does not provide a link between the administration of double fermented grain and treating diabetics, the Examiner asserts that Tölle discloses that the grains should be consumed over a period of time and thus the blood sugar lowering effect will be inherent to the consumption. With regard to Applicants' argument that the blood sugar decreasing effect is due to consumption and not due to weight loss, the examiner asserts that the lowering of blood sugar values would be concomitant with losing weight as disclosed in Tölle and that the present claims are drawn to the use of an identical product. Applicants respectfully disagree and traverse the rejections.

With regard to the assertion that Tölle discloses using distillers grains as food supplement over extended periods of time, Applicants submit that the plain wording of column 2, starting on line 49 of Tölle, recommends the use of Tölle's products as supplementary diet during slimming cures and is clearly linked to modified products where honey is sprayed onto the product. Thus, – contrary to the Examiner's assertions, Tölle does not disclose the use of the unmodified distillers grains as supplementary food component for consumption over extended periods of time. Furthermore, by spraying honey onto the distillers grains the sugar content thereof is increased, which one would not do in a method of reducing the blood sugar levels of patients. Moreover, honey-sprayed products are no longer recommended for diabetics. Thus, Applicants submit that the assertion that Tölle suggested using the products as supplementary food complements is flawed as this disclosure in Toelle does not refer to the unmodified distillers grains.

Furthermore, Applicants submit that the phrase "suitable for diabetics" does not implicitly or inherently disclose that the respective product would be suitable for reducing the blood sugar level when consumed. Rather, it simply says that the product may be consumed by diabetes patients without increasing the blood sugar level significantly. This, however, has nothing to do with using such a product for actually lowering a patient's blood sugar level.

Applicants traverse the Examiner's reliance on inherency as the basis for Tölle's anticipation of the present claims because the claims are directed to a method which is not taught by Tölle. The Examiner has not addressed Applicants' argument that Tölle does not disclose an "effective" dose at all, or "an amount effective to lower said

patient's increased blood sugar value" as recited in claim 32. Rather, the Examiner has again stated that Tölle discloses that doses of 21-25 grams are effective doses. The dosage range determined in Tölle is based only on research to decrease "disturbing flavor" in order to prepare a formulation that yields "tasty selling units." Moreover, the alleged effective dose of 21-25 g in Tölle is not disclosed in the manner of a dosage at all because it is not defined as an amount to be administered to patients, but rather only as a weight of grains to include along with additional ingredients to produce a ready to consume product having a weight of 200 to 250 grams. Thus, the amount disclosed in Tölle is effective only for making a tasty food product, e.g., by dilution and honey-spray, but there is no hint of administration regimen or blood sugar value-reducing effect to be obtained thereby. Thus, Applicants submit that because the recited feature of administering to the patient "an amount effective to lower said patient's increased blood sugar value" was not disclosed in Tölle, the claims are not anticipated for at least this reason.

For similar reasons, Tölle does not anticipate dependent claims 39 or 40, which require the step of administering a daily dose of 100 to 400 g of distillers grains, and administering 2 to 5 individual daily doses of the distillers grains, respectively. Accordingly, Applicants respectfully request that the rejection of claims 39 and 40 be withdrawn for these additional reasons.

<u>When there is no hint of dosage regimen or therapeutic outcome, a prior art reference does not disclose a method of treating patients.</u>

The Federal Circuit has recently confirmed that in order to anticipate a method of treatment, the prior art reference must "enable a person of ordinary skill in the art to treat [the disease] with [the compound]…." *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (finding no anticipation when prior art patent did not provide sufficient direction or guidance to prescribe a treatment regimen). The factors to be considered when determining whether an allegedly anticipatory reference would have enabled a person of ordinary skill in the art to use the claimed method are (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *Id.* at 1315 (citing *In re Wands,* 858 F.2d 731, 737 (Fed.Cir.1988)). Here, the Tölle reference provides no mention of a therapeutic dosage, treatment objective, therapeutic outcome, or a working example. Thus, Tölle clearly does not provide sufficient guidance to persons of ordinary skill to practice the claimed method. Based on Tölle, a person of ordinary skill would not have been able to predict that administering a composition comprising distillers grains which have been fermented with a yogurt culture and/or a butter culture in an effective amount would have a blood sugar value-lowering effect in patients having a fasting blood sugar value of ≥ 110 mg/dl or in patient's having postprandial blood sugar value of ≥ 140 mg/dl. A person of ordinary skill in the art would also not have been able to predict what amount constituted an "effective amount." Rather, it would have required undue experimentation for a person of ordinary skill to identify distillers grains which have been fermented with a yogurt

culture and/or a butter culture as a treatment for increased blood sugar values and to devise appropriate dosage parameters. Accordingly, based on the above arguments and the relevant caselaw, it is clear that Tölle does not anticipate the present claims.

In order to make a proper rejection under § 102, "each and every" method step must be disclosed "identically" in the asserted reference. *See, e.g.*, *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim."); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). The steps of testing patients for specific blood sugar values and administering effective amounts of the grains based on those values are not disclosed by Tölle. Accordingly, because there is no disclosure for each of the recited steps and features of the instant claims, the Examiner has not carried the burden of showing anticipation.

In view of the foregoing, Applicants respectfully submit that the independent claims patentably define the present invention over Tölle. Further, the dependent claims should also be allowable for the same reasons as their respective base claims and further due to the additional features that they recite. Applicants respectfully request that the rejections be withdrawn.

Conclusions

In view of the above amendments and remarks hereto, Applicants believe that all of the Examiner's rejections set forth in the May 10, 2011 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants, therefore, believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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